

REMARKS

The September 13, 2007, Official Action has been carefully reviewed. In light of the following amendments and remarks, favorable reconsideration and allowance of the application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three (3) months was set forth in the September 13, 2007, Official Action. Therefore, the initial due date for response is December 13, 2007. A petition for a one (1) month extension of time is presented with this response, which is being filed within the one month extension period.

As another preliminary matter, Applicant notes that prosecution on the merits of claims 2, 12, 15-16, and 67-71 has been reopened in view of the new rejections raised under 35 U.S.C. §112, first paragraph. Applicants are disappointed that claims 68-71, which were previously indicated to be in condition for allowance in the Office Action dated June 12, 2007, have now withdrawn from consideration as being directed to a non-elected invention. The Examiner has indicated that claim 2 is directed to allowable subject matter and has further rejected claims 12, 15, 16, and 67.

The Examiner has also objected to claim 16 as being dependent upon a rejected base claim but has indicated that claim would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. Claim 16 has been amended to properly depend from claim 12, thereby rendering this objection moot. Claim 16 has been further amended to specify that stroke damage to the CNS is to be treated. Support for this amendment can be found in claim 16 as originally filed and

at page 11, lines 33-35.

Turning to the substantive aspects of the September 13, 2007, Official Action, the Examiner has rejected claims 12, 15, 67 under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. Specifically, the Examiner contends that the claims refer to a peptide only by function.

At page 5 of the Official Action, claims 12, 15, and 67 have been rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly does not provide reasonable enablement for the claimed subject matter.

Lastly, claim 16 stands rejected under 35 U.S.C. §112, first paragraph, since it allegedly does not provide enablement for a method of treating stroke damage in a patient by injecting the composition of SEQ ID NO: 1.

The foregoing rejections constitute all of the grounds set forth in the September 13, 2007, Official Action for refusing the present application. In view of the amendments and arguments set forth in this response, Applicant respectfully submits that the rejections under 35 U.S.C. §112, first paragraph, of claims 12, 15-16, and 67 as set forth in the September 13, 2007, Official Action cannot be maintained.

CLAIMS 12, 15, AND 67, AS AMENDED, SATISFY THE WRITTEN DESCRIPTION REQUIREMENT OF 35 U.S.C. § 112, FIRST PARAGRAPH

The Examiner has maintained the rejection of claims 12, 15, and 67 for failing to satisfy the written description requirement of 35 U.S.C. §112, first paragraph. It is the Examiner's position that the claims contain subject matter which was not described in such a way as to

reasonably convey to a skilled artisan that the inventor had possession of the claimed invention at the time of filing the application. Specifically, the Examiner asserts that the claims refer to a peptide only by function.

Applicant respectfully disagrees with the Examiner's position for the reasons already of record. Applicant reiterates that it is well within the purview of the skilled artisan to design peptide variants having the core sequence and slight variations thereof up to 10 amino acids in length which function as specified in the claims. However, in the interest of expediting prosecution of the instant application, Applicant has amended claims 12 and 67 in accordance with the proposed Examiner's Amendment which was faxed to the undersigned on September 5, 2007, to include the limitation that the peptide is "up to 8 amino acids in length" comprising the amino acid sequence of YLTQPQS (SEQ ID NO: 1). Claim 15 incorporates this amendment through its dependency on claim 12. Applicant submits that the Examiner has previously determined that this subject matter complies with the written description requirement of the statute. In light of the foregoing claim amendments, it cannot be reasonably maintained that the specification does not provide a full written description of the claimed subject matter to satisfy 35 U.S.C. §112, first paragraph, and Applicant respectfully requests that the rejection of claims 12, 15, and 67 be withdrawn.

CLAIMS 12, 15, AND 67, AS AMENDED, SATISFY THE ENABLEMENT REQUIREMENT OF 35 U.S.C. § 112, FIRST PARAGRAPH

The Examiner has rejected claims 12, 15, and 67 for failing to satisfy the enablement requirement of 35 U.S.C.

§112, first paragraph. Specifically, the Examiner asserts that the specification fails to provide the requisite guidance for making and /or using the claimed invention, and that undue experimentation would be required to practice the invention as claimed.

Applicant continues to dispute the Examiner's contention that practice of the invention claimed in 12, 15, and 67 requires undue experimentation. However, in the interest of expediting prosecution of the instant application, Applicant has amended claims 12 and 67 to recite that the peptide is "up to 8 amino acids in length." Applicant notes, as above, that this language appears on the proposed Examiner's Amendment faxed to the undersigned on September 5, 2007 and has previously been indicated as fully described and enabled by the Examiner.

In light of all the foregoing, Applicants submit that the present claims satisfy the requirements of 35 U.S.C. §112, first paragraph. Accordingly, the rejection of claims 12, 15, and 67 for inadequate enablement is untenable and should be withdrawn.

**CLAIM 16, AS AMENDED, SATISFIES THE REQUIREMENTS OF 35
U.S.C. §112, FIRST PARAGRAPH**

The Examiner has newly rejected claim 16 under 35 U.S.C. §112, first paragraph as allegedly lacking enablement. Specifically, it is the Examiner's position that the specification does not enable a method of treating stroke damage in a patient, and therefore, a skilled artisan cannot make and use the invention.

At page 7 of the Office Action, the Examiner asserts "although stroke is a disease of the brain, it can affect the entire body," and the Examiner lists several physical

symptoms suffered by stroke patients. Applicant submits that **CNS stroke damage** comprises the molecular changes in signal transduction pathways in the brain. Accordingly, Applicant has amended claim 16 to refer to "CNS stroke damage," and added claims 72 which is supported by the original disclosure at page 9, lines 11-16 and does not introduce new matter.

Thus, the claim no longer reads on treating stroke damage in the entire body. Applicant submits that stroke damage results in release of neuronal growth inhibitory molecules, e.g., Nogo and MAG, that enter the CNS environment and inhibit the growth of neuronal cells following stroke. Consequently, as the Applicant has disclosed, blocking the effects of these inhibitory molecules should facilitate the regeneration of neurons following CNS stroke damage or any other CNS damaging event.

In support of the foregoing contention, submitted herewith is a reference containing data which support the efficacy of Nogo-A blockade as a treatment for ischemic stroke and implicate plasticity from the unlesioned hemisphere as a mechanism for recovery." See Papadopoulos et al., Ann. Neurol. (2002) 51:433-441, abstract.

Likewise, Wiessner et al. is another reference which presents results that "support the concept that Nogo-A neutralization augments the inherent and functionally meaningful plastic capacity of the adult CNS, which is restricted by outgrowth inhibitors." J. Cereb. Blood Flow & Metab. (2003) 23:154-165. As shown by Applicant, SEQ ID NO: 1 can bind to one or more of neuronal growth inhibitory molecules described in these references and thus diminish the deleterious effects of molecules like Nogo. Such a

reduction should facilitate neuronal regeneration processes.

In light of the foregoing remarks and claim amendment, Applicant respectfully requests that the above-mentioned rejection of claim 16 under 35 U.S.C. §112, first paragraph be withdrawn.

CONCLUSION

It is respectfully requested that the amendments presented herewith be entered in this application. These amendments and remarks are believed to clearly place the pending claims in condition for allowance. Therefore, it is respectfully urged that the rejections set forth in the September 13, 2007, Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned at the phone number give below.

Respectfully submitted,

DANN DORFMAN HERRELL and SKILLMAN, P.C.

Attorneys for Applicant

By Kathleen D. Rigaut

Kathleen D. Rigaut, Ph.D., J.D.
PTO Registration No. 43,047

Telephone: (215) 563-4100

Facsimile: (215) 563-4044

Enclosures: 1) Wiesnner et al., J. Cereb. Blood Flow & Metab. (2003) 23:154-165.

2) Papadopoulos et al., Ann. Neurol. (2002)
51:433-441